IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/692,031
Confirmation No.:	5358
First-Named Inventor:	William F. Crismore
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Group Art Unit:	1797
Examiner:	Alexander, Lyle
Attorney Docket No.:	007404-000571
Title:	ELECTROCHEMICAL BIOSENSOR TEST STRIP

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Notice of Appeal received by the United States Patent Office on July 9, 2009 in connection with the above-indicated application, an Appeal Brief according to 37 CFR §41.37 is provided along with the requisite fee of $540 for a large entity.

A request for a three-month extension of time along with the requisite fee has been enclosed with this Appeal Brief.

The Commissioner is authorized to grant any further extensions of time and charge any deficiency or credit any overpayment to Deposit Account No. 23-3030 but not to include issue fees.

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I. REAL PARTY IN INTEREST

(37 CFR §41.37(c)(1)(i))

The real parties in interest in this appeal are Roche Diagnostics Operations, Inc. and Roche Operations Ltd, which are the owners of the present application by written assignments recorded at the United States Patent and Trademark Office as follows:

- From inventors William F. Crismore, Nigel A. Surridge, Daniel R. McMinn, Richard J. Bodensteiner, Eric R. Diebold, R. Dale Delk, David W. Burke, Jiaxiong Jason Ho, Robert Kitchel Earl, and Brian A. Heald to Boehringer Mannheim Corporation, recorded at Reel 020412, Frame 0568.
- Roche Diagnostic Systems, Inc. and Boehringer Mannheim Corporation merged to become Roche Diagnostics Corporation, recorded at Reel 020283, Frame 0547.
- From Roche Diagnostics Corporation to Roche Diagnostics Operations, Inc., recorded at Reel 015201, Frame 0368 and Reel 020410, Frame 0958.
- From Roche Diagnostics Operations, Inc., a one-half interest to Corange International Limited, recorded at Reel 019419, Frame 0381.
- A change of name from Corange International Limited to Roche Operations Ltd., recorded at Reel 022634, Frame 0371.

II. RELATED APPEALS AND INTERFERENCES

(37 CFR §41.37(c)(1)(ii))

The Applicant, the Applicant's legal representative, and the assignees are unaware of any related appeals or interferences which will affect, be directly affected by, or have a bearing on the Appeal Board's decision in the present appeal.

III. STATUS OF CLAIMS

(37 CFR §41.37(c)(1)(iii))

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are 68-104.

B. STATUS OF ALL THE CLAIMS

1. Claims canceled: 1-67.
2. Claims withdrawn from consideration but not canceled: None.
3. Claims allowed: None.
4. Claims rejected: 68-104.
5. Claims objected to: none.

C. CLAIMS ON APPEAL

The claims on appeal are 68-104.

IV. STATUS OF AMENDMENTS

(37 CFR §41.37(c)(1)(iv))

An amendment after the non-final rejection was submitted on December 23, 2008 in which claims 68-104 were presented. In the March 9, 2009, Office Action, the amendment was entered. Remarks for Pre-Appeal Brief Review were submitted on July 9, 2009. In the August 6, 2009, Notice of Panel Decision from Pre-Appeal Brief Review, the present application remains under appeal and claims 68-104 remain rejected. No amendments subsequent to the August 6, 2009, Notice of Panel Decision from Pre-Appeal Brief Review have been submitted.

V. SUMMARY OF CLAIMED SUBJECT MATTER

(37 CFR §41.37(c)(1)(v))

The following summarization explains how each of the independent claims reads on one or more embodiments of the present application. The present application is a divisional of U.S. Patent Application No. 10/008,788, which is a reissue of U.S. Patent Application No. 08/985,840, now U.S. Patent No. 5,997,817. In this summarization, all FIG. designations refer to U.S. Patent No. 5,997,817, and all column and line numbers refer to the corresponding text of U.S. Patent No. 5,997,817. It should be appreciated that the below summaries are to be interpreted as merely nonlimiting examples--it being understood that all other embodiments upon which the claims read are also intended to be covered.

The present application provides a uniquely advantageous design for a capillary fill test strip in which the filling of the strip is viewable to show if adequate filling has occurred to conduct a test. Test strips which do not adequately fill can produce inaccurate results. The present application provides an elegant solution to this problem by allowing the users to visually watch the blood fill the test strip and readily determine whether the blood makes it to the fill line—the indicator when at least enough blood has been added to conduct a test.

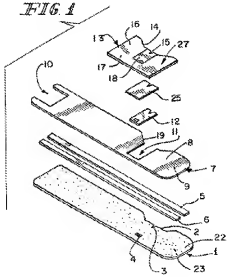
All of the claims of the present application include the combination of a solid, transparent, or translucent viewing material which overlies an internal capillary chamber and a fill line. In other words, a blood sample can be viewed through the solid, transparent, or translucent viewing material as the sample fills a capillary channel inwardly from the edge of a test strip to the fill line or finish line. Claims 68, 82 and 96 describe a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be

visualized through the solid, transparent, or translucent material to provide confirmation to the user that a sufficient amount of blood has been dosed to the strip and has reached the required test area, such that the test results can be accurate. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip.

A. Independent Claim 68

Independent claim 68 sets forth an apparatus that reads on at least one embodiment of the present application. In particular, FIGS. 1, 2, 3i, 4, and 5 are reproduced below. Claim 68 (See *infra* Table A) describes an electrochemical test strip that includes a strip body (1, 5, 6, 7, and 13), working (5) and counter (6) electrodes, a test reagent (12), visualization means including a solid, transparent, or translucent viewing material (18), and a fill line (end portion of 18) that extends across the solid, transparent, or translucent viewing material (18) as illustrated in FIG. 1.

FIG. 1



As shown in FIG. 2, the strip body (1, 5, 6, 7, and 13) includes first insulating substrate (1), working (5) and counter (6) electrodes, second insulating substrate (7), and roof (13) sandwiched together.

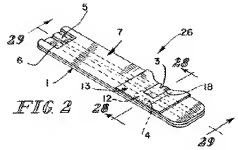


FIG. 2

The assembled strip body has an edge surface that extends about the perimeter of the strip body. A capillary channel is defined by second surface (17) of roof (13), the edges of opening (11), and first surface (22) of insulating substrate (1) (and conductive tracks (5) and (6) affixed to first surface (22) of substrate (1)). The length and width of this capillary channel are defined by the length and width of opening (11) and the height of the channel is defined by the thickness of second insulting substrate (7). First insulating substrate (1) further includes a vent hole (4), illustrated in FIGS. 1 and 2.

The sample application port (20) is illustrated in FIG. 4, which is a cross-sectional view of the test strip of FIG. 2 through line 28-28. The sample application port (20) is the entrance of the capillary channel for the blood sample.

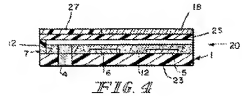


FIG. 4

Working (5) and counter (6) electrodes are spaced from each other and positioned within the capillary channel as illustrated in FIGS. 1 and 4. A test reagent (12) is adjacent the working electrode (5).

The roof (13) is made of a solid, transparent, or translucent viewing material. An opaque ink is printed on first surface (16) in a pattern (27) such that a window (18) remains transparent or translucent. (Col. 8, lines 27-29) The window (18) is positioned and dimensioned so that

when the roof (13) is affixed to surface (8), it will align with opening (11) as shown in FIGS. 3i and 5.

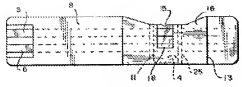


FIG 3i

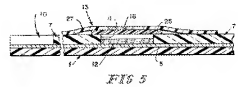


FIG 5

The solid material for the roof (13) is distinguished from the prior art references discussed below that simply have an opening or hole that is exposed to the outside without a solid material providing visualization of a blood sample as it fills an interior capillary chamber. Moreover, these prior art references require the opening as the mechanism for filling the test strips with a body fluid sample.

Illustrated in FIGS. 3i and 4, the fill line is produced by the interface of the opaque ink that forms pattern (27) printed on the roof (13) and the translucent or transparent window (18) formed by the absence of opaque ink on the roof (13). The window (18) is defined in FIG. 3i by the pair of solid parallel lines that extend from near notch (15) and a horizontal solid line that is positioned near the end of the leader line for the reference number (18) in FIG. 3i. The fill line is also shown in FIG. 4 as the vertical line or intersection between pattern (27) and window (18). The fill line extends across the capillary channel at a location intermediate the length of the capillary channel, i.e., at some predetermined location that ensures that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

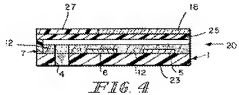


FIG. 4

Table A is included to assist the Board in locating support for each claim element.

Table A

Claim 68 Element (example reference characters in parentheses)	Location of Supporting Text and/or Drawings in the Application
An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:	See FIGS. 1, 2, 3i, 4, and 5. Also see: Col. 3, lines 1-2: "First insulating substrate 1 further includes indentation 2, notch 3, and vent hole 4."
a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port to at least the vent;	Col. 4, lines 36-48: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber. The length and width of this capillary chamber are defined by the length and width of opening 11 and the height of the chamber is defined by the thickness of second insulting substrate 7." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface;	Col. 3, lines 32-34: "Electrically conductive tracks 5 and 6 represent the electrodes of the biosensor test strip. These electrodes must be sufficiently separated…" Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least the working electrode; and	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to those exposed surfaces of tracks 5 and 6." Col. 4, lines 19-23: "Further, the entire exposed area of an electrode may not need to be covered with test reagent as long as a well defined and reproducible area of the electrode is covered with reagent."
visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent, or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a "fill to here" line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, line 67 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces

	the chances of erroneous test results due to underdosing of a test strip." Col. 2, lines 7-10: "The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
said visualization means further includes a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 63-67: "The second new feature is a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 8, line 63 to col. 9, line 4: "it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered."

B. Independent Claim 82

Independent claim 82 sets forth an apparatus that reads on at least one embodiment of the present application. Claim 82 is similar to claim 68; however, claim 82 includes filling a viewing area at least up to a portion of a counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test.

Table B is included to assist the Board in locating support for each claim element.

Table B

Claim 82 Element (example reference characters in parentheses)	Location of Supporting Text and/or Drawings in the Application
An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising:	See FIGS. 1, 2, 3i, 4, and 5. Also see:
a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port at least to the vent;	Col. 3, lines 1-2: "First insulating substrate 1 further includes indentation 2, notch 3, and vent hole 4." Col. 4, lines 36-48: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber. The length and width of this capillary chamber are defined by the length and width of opening 11 and the height of the chamber is defined by the thickness of second insulting substrate 7." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface; and	Col. 3, lines 32-34: "Electrically conductive tracks 5 and 6 represent the electrodes of the biosensor test strip. These electrodes must be sufficiently separated…" Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least the working electrode;	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to those exposed surfaces of tracks 5 and 6." Col. 4, lines 19-23: "Further, the entire exposed area of an electrode may not need to be covered with test reagent as long as a

	well defined and reproducible area of the electrode is covered with reagent."
a solid, transparent, or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode, the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test,	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a "fill to here" line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, line 67 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 2, lines 7-10: "The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
said strip body further including a fill line extending across the viewing area at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 63-67: "The second new feature is a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test."

	Col. 8, line 63 to col. 9, line 4: "it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered."

C. Independent Claim 96

Independent claim 96 sets forth an apparatus that reads on at least one embodiment of the present application. Claim 96 is similar to claim 68; however, claim 96 further defines the strip body also includes opaque portions that define a fill area viewable through the viewing material. This fill area comprises an area of the capillary channel needed to be filled to conduct an accurate test.

Table C is included to assist the Board in locating support for each claim element.

Table C

Claim 96 Element (example reference characters in parentheses)	Location of Supporting Text and/or Drawings in the Application
An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge surface, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;	See FIGS. 1, 2, 3i, 4, and 5. Also see: Col. 3, lines 1-2: "First insulating substrate 1 further includes indentation 2, notch 3, and vent hole 4." Col. 4, lines 36-48: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber. The length and width of this capillary chamber are defined by the length and width of opening 11 and the height of the chamber is defined by the thickness of second insulting substrate 7." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
at least working and counter electrodes spaced from	Col. 3, lines 32-34:

each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge surface;	"Electrically conductive tracks 5 and 6 represent the electrodes of the biosensor test strip. These electrodes must be sufficiently separated…" Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to those exposed surfaces of tracks 5 and 6." Col. 4, lines 19-23: "Further, the entire exposed area of an electrode may not need to be covered with test reagent as long as a well defined and reproducible area of the electrode is covered with reagent."
said strip body including a solid, transparent, or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area; said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; and	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a "fill to here" line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, line 67 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 2, lines 7-10: "The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in

	a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test. wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 63-67: "The second new feature is a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 8, line 63 to col. 9, line 4: "it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered."

It is apparent from the foregoing claim tables, and particularly the quoted passages from the specification, that the application sufficiently discloses the concept claimed herein, that being the provision of a line demarcated on a test strip, which indicates to where the blood sample must fill in order to conduct a test. More particularly, the specification clearly discloses the concept of shading an area surrounding the capillary channel such that it is apparent to the user that the area viewable as the blood fills the capillary channel is the area that must be filled for the test strip to be adequately dosed. This is in contrast to prior art devices, discussed in more detail hereafter, for which the user may be able to see blood sample entering into the test strip, but the user can not distinguish whether the correct area, and the total required area, of the test strip is filled at the time of testing. If the user can see too much of the strip interior, to the extent that the user can

not tell which portions of that interior need not be filled, then the strip does not convey to the user whether the strip has been adequately dosed.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(37 CFR § 41.37(c)(1)(vi))

A concise statement of each ground of rejection presented for review is provided below.

A. Claims 68-104 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

B. Claims 68-104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,437,999 (Diebold).

C. Claims 68-104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,942,102 or 6,174,420 (Hodges).

D. Claims 68-104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,798,031 (Charlton).

E. Claims 68-104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,575,895 (Ikeda) or U.S. Patent No. 5,264,103 (Yoshioka).

F. Claims 68-104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,027,692 (Galen).

G. Claims 68-104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,684,445 (Seshimoto), U.S. Patent No. 4,473,457 (Columbus), or U.S. Patent No. 5,798,031 (Ikeda).

VII. ARGUMENT

(37 CFR § 41.37(c)(1)(vii))

The contentions of the Applicant and the basis for those contentions with respect to each ground of rejection are presented below.

A. Rejection Under 35 U.S.C. § 112, First Paragraph

1. Independent Claims 68, 82, and 96

Claims 68-104 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. As noted in the March 9, 2009, Office Action, "The original specification… does not teach a 'fill line' to determine the proper amount of sample. Rather, it appears the patent teaches an area where the user can see if the proper amount of sample is present."

In traversal, the Applicant submits that the Patent Office has failed to meet this burden by failing to show that claims 68-104 do not satisfy the written description requirement.

"The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in [the] specification disclosure a description of the invention defined by the claims." *Ex parte Sorensen*, 3 U.S.P.Q.2d 1462, 1463 (BPAI 1987) (*citing In re Wertheim*, 191 U.S.P.Q. 90 (CCPA 1976). "To fulfill the written description requirement, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed." *Cordis Corp. v. Medtronic AVE Inc.*, 67 U.S.P.Q.2d 1876, 1885 (Fed. Cir. 2003).

However, the disclosure as originally filed does **not** have to provide *in haec verba* or **exact language support** for the claimed subject matter at issue. *See, Id.* and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996). (emphasis added) Rather, as noted in §2163 of the MPEP, "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)." The "written description" is not limited to text, but also includes the drawings in the application, and the drawings can provide adequate description by themselves. *Cooper Cameron Corp. v. Kvaerner Oilfield Prods.*, 62 U.S.P.Q.2d 1846, 1850 (Fed. Cir. 2002).

Notably, the courts have stated that written description is "relatively simple to comply with and thus will ordinarily demand minimal concern on the part of the Patent Office." *In re Moore*, 169 U.S.P.Q. 236, 238 (CCPA 1971). A *prima facie* case for this rejection must do more than merely point out a lack of explicit recitation of a claim phrase. *See In re Wright*, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989) (that the exact words at issue are not in the specification "is not important").

Applicant submits the following comments and cites to the specification in support of the claims, including specific reference to the disclosure of a "fill line" as called for in the claims. However, the exact language support for the claimed subject matter at issue ("fill line") is not required in the disclosure as originally filed to satisfy the written description requirement. *Fujikawa*, 93 F.3d at 1570. Applicant also includes FIGS. 1, 2, 3i, 4, and 5, again, to illustrate the "fill line" since the drawings can provide adequate written description by themselves.

Cooper Cameron Corp., 62 U.S.P.Q.2d at 1850. Applicant therefore believes that the claims are sufficiently supported under 35 U.S.C. § 112, first paragraph.

General support for the claims, including the provision of a "fill line", is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly FIGS. 1, 2, 3i, 4, and 5), and the Disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. Portions of the specification are repeated and discussed below.

Abstract, lines 11-15:
"The roof of the capillary test chamber includes **a transparent or translucent window which operates as a *'fill to here' line***, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test."

Col. 1, line 61 to Col. 2, line 14:
"The second new feature is a transparent or translucent window which operates as ***a 'fill to here' line***, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test. **The window defines the minimum sample amount, or dose, required to accurately perform a test**, and, therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip.

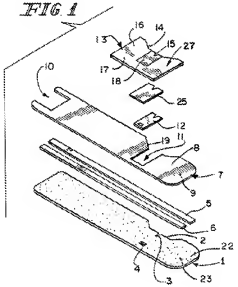
The length and width of the window are shorter than the length and width of the capillary test chamber. The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip. Preferably, the area of the roof surrounding the window is colored in a way that provides good color contrast between the sample, as observed through the window, and the roof area surrounding the window for ease of identifying sufficient dosing of the strip."

Col. 4, lines 36-41:
"Preferably, roof 13 further includes transparent or translucent window 18. Window 18 is dimensioned and positioned so that when roof 13 is affixed to second insulating substrate 7, the window overlays the entire width of conductive track 5 and at least about ten percent of the width of conductive track 6."

Col. 8, line 55 to col. 9, line 9:
"The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should

expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, **it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample**. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."

As illustrated in Fig. 1, roof (13) includes transparent or translucent window (18). Window (18) is clearly demarcated with one pair of opposing sidelines, a sample receiving edge that may include notch (15), and a "fill line" opposite the sample receiving edge.



As illustrated in FIGS. 2 and 3i, window (18) is assembled with the biosensor; however, the boundaries of the window (18) are clearly illustrated and depict a "fill line" across from or substantially parallel to the sample or dose receiving edge.

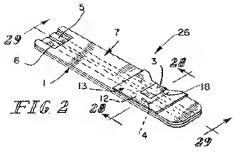


FIG 2

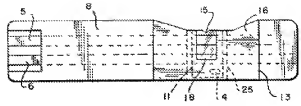


FIG 3i

To use the biosensor, a body fluid sample enters the sample application port (20) (see FIG. 4) at the sample receiving edge and the body fluid sample continues to travel along the capillary channel.

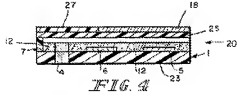


FIG. 4

A portion of the body fluid sample is visible through the transparent or translucent window (18). The "fill line" is represented in FIG. 4 as the vertical line separating window (18) and pattern (27) on roof (13). The window (18) defines the minimum sample amount, or dose, required to accurately perform a test.

As the body fluid sample reaches the "fill line" on window (18), the user can visually identify a sufficient filling of the test strip or biosensor for conducting a test.

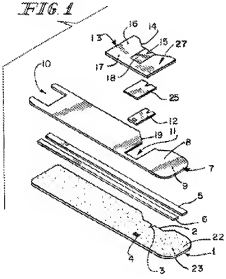
Applicant submits that it is apparent the application as originally filed sufficiently discloses the concept claimed herein, that being the provision of a "fill line" or a line demarcated on a test strip which indicates to where the body fluid or blood sample must fill in order to conduct a test.

2. Dependent Claims 69, 83, and 97

Dependent claims 69, 83, and 97 further define the position of the "fill line" as the "fill line is formed by an opaque portion overlying a portion of the capillary test chamber."

Col. 8, lines 27-32:
"A substantially **opaque** ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."

Illustrated in FIGS. 1 and 4, the "fill line" is produced by the interface of the opaque ink that forms pattern (27) printed on first surface (16) of roof (13) and the translucent or transparent window (18) formed by the absence of opaque ink on the roof (13).



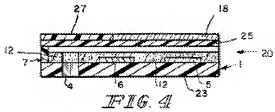


FIG. 4

As shown in FIG. 4, the "fill line" is the vertical line between window (18) and pattern (27) in roof (13). The "fill line" is represented graphically as the vertical line between the two different patterns of cross-hatching in FIG. 4.

Applicant submits that it is apparent the application as originally filed sufficiently discloses the concept claimed herein, that being the provision of a "fill line" wherein the "fill line is formed by an opaque portion overlying a portion of the capillary test chamber."

3. Dependent Claims 70, 84, and 98

Dependent claims 70, 84, and 98 further define the position of the "fill line" as the "fill line extends at a location between the working electrode and the vent."

Col. 2, line 63 – Col. 3, line 2:
"The biosensor includes first insulating substrate 1, which has first surface 22 and second surface 23. Insulating substrate 1 may be made of any useful insulating material. ... First insulating substrate 1 further includes indentation 2, notch 3, and vent hole 4."

Col. 3, lines 38-42:
"In the test strip shown in FIG. 1, electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."

Col. 4, lines 35-41:
"Preferably, roof 13 further includes transparent or translucent window 18. Window 18 is dimensioned and positioned so that when roof 13 is affixed to second insulating substrate 7, the window overlays the entire width of conductive track 5 and at least about ten percent of the width of conductive track 6."

As illustrated in FIG. 4, the "fill line" is positioned between working electrode (5) and vent hole (4).

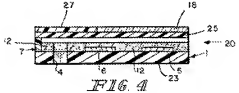


FIG. 4

Applicant submits that it is apparent the application as originally filed sufficiently discloses the concept claimed herein, that being the provision of a "fill line" wherein the "fill line extends at a location between the working electrode and the vent."

B. Rejection Under 35 U.S.C. §102(b) By U.S. Patent No. 5,437,999 (Diebold).

1. Office Action

The March 9, 2009, Office Action asserts that Diebold teaches the same structure of a device with cut out portions, a vent and reagents associated with the electrodes. March 9, 2009, Office Action, Pages 3-4.

2. Diebold Reference

Generally, Diebold teaches an electrochemical sensor with an opposing electrode design illustrated in FIGS. 5 and 6, reproduced below. (Col. 8, lines 15-18) A reference or counter electrode element (48) is spatially displaced from working electrode element (11) by spacer (43). First cutout portion (44) in spacer (43) forms capillary space (49) when situated between reference or counter electrode element (48) and working electrode element (11). (FIG. 5; Col. 8, lines 23-27)

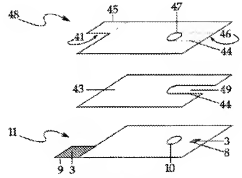


Fig. 5

"In assembled electrochemical sensor 52 shown in FIG. 6, capillary space 49 (shown in phantom lines) has first opening 50 at one edge of the electrochemical sensor." (Col. 8, lines 37-40). As illustrated in FIG. 6, the capillary space (49) is illustrated only in phantom lines to illustrate the capillary space (49) is hidden and not viewable through either reference/counter electrode element (48) or working electrode element (11). In other words, neither

reference/counter electrode element (48) nor working electrode element (11) consists of a transparent or translucent viewing material.

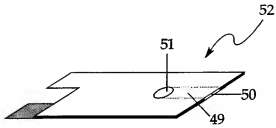


Fig. 6

"In use, a sample containing an analyte to be detected or measured may be introduced into capillary space 49 of electrochemical sensor 52 through either opening 50 or vent port 51. In either case, the sample is spontaneously drawn into the electrochemical sensor by capillary action. *As a result, the electrochemical sensor automatically controls the sample volume measured without user intervention.* In addition, since the sample is totally contained within capillary space 49..." (Col. 8, lines 45-56)

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Diebold. Although claims 68 to 81 are individually patentable over Diebold, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Diebold does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Diebold

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

It is well settled law that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); See MPEP § 2131. Additionally, "[t]he identical invention must be shown in as complete detail as is contained in the … claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). It is not sufficient that the prior art reference disclose all of the elements in isolation. Rather, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinefabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 U.S.P.Q 481, 485 (Fed. Cir. 1984, emphasis added). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1459 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate. Moreover, "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." MPEP § 2111 (*citing In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999)).

Further, ample, and long-standing precedent explains that functional language in a claim is to be given patentable weight by the Examiner. *See, e.g., In re Atwood*, 148 U.S.P.Q. 203, 210

(CCPA 1966) ("limitations ignored by the Board as use limitations we think are functional expressions which must be given weight"); *In re Ludtke*, 169 U.S.P.Q. 563, 566 (CCPA 1971); *K-2 Corp. v. Salomon S.A.*, 52 U.S.P.Q.2d 1000, 1004 (Fed. Cir. 1999). For anticipation to exist, the Examiner must show every element, including functionally recited features.

Diebold fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Diebold shows a reference/counter electrode element (48) spatially displaced from a working electrode element (11) by spacer (43). Diebold does not disclose that either reference/counter electrode element (48) or working electrode element (11) consist of a transparent or translucent viewing material that overlies a capillary channel. Moreover, neither reference/counter electrode element (48) nor working electrode element (11) includes "said visualization means further includes a fill line extending across the capillary channel…"

Additionally, claims 68 to 81 are neither anticipated by Diebold nor rendered obvious by Diebold because Diebold teaches away from any visualization means, and hence user intervention, associated with capillary space (49) and the electrochemical sensor. Instead, Diebold teaches "the electrochemical sensor automatically controls the sample volume measured *without user intervention*." (Col. 8, lines 53-55, emphasis added) Therefore, a proper case of

anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Diebold. Although claims 82 to 95 are individually patentable over Diebold, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Diebold does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Diebold

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Diebold fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Diebold does not disclose that either reference/counter electrode element (48) or working electrode element (11) consist of a transparent or translucent viewing material that extends from about the sample application port and overlying the capillary channel.

Moreover, neither reference/counter electrode element (48) nor working electrode element (11) includes "***a fill line extending across the viewing area*** ..." There are no lines of demarcation disclosed in Diebold. (emphasis added)

Additionally, claims 82 to 95 are neither anticipated by Diebold nor rendered obvious by Diebold because Diebold teaches away from a viewing area having a fill line on the electrochemical sensor. Instead, Diebold teaches "the electrochemical sensor automatically controls the sample volume measured *without user intervention*." (Col. 8, lines 53-55, emphasis added) In other words, a viewing area would not be required or desired since Diebold teaches away from user intervention in any form. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Diebold. Although claims 96 to 104 are individually patentable over Diebold, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104, and asserts that Diebold does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Diebold

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Diebold fails to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Diebold does not disclose that either reference/counter electrode element (48) or working electrode element (11) consist of a transparent or translucent viewing material that overlies the capillary channel. Moreover, neither reference/counter electrode element (48) nor working electrode element (11) includes "a fill line extending across the capillary channel ..." There are no lines of demarcation disclosed in Diebold.

Additionally, claims 96 to 104 are neither anticipated by Diebold nor rendered obvious by Diebold because Diebold teaches away from a transparent or translucent viewing material having a fill line on the electrochemical sensor. Instead, Diebold teaches "the electrochemical sensor automatically controls the sample volume measured *without user intervention*." (Col. 8, lines 53-55, emphasis added) In other words, transparent or translucent viewing material having a fill line would not be required or desired since Diebold teaches away from user intervention in any form. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

C. Rejection Under 35 U.S.C. §102(e) By U.S. Patent No. 5,942,102 or 6,174,420 (Hodges '102 and Hodges '420).

1. Office Action

The March 9, 2009, Office Action asserts that Hodges '102 and Hodges '420 teach an electrochemical test device for determination of glucose in blood. March 9, 2009, Office Action, Page 4. The Office Action asserts Hodges '102 teaches a working electrode (2), a counter electrode (16), and a dried reagent. "The device is assembled between two layers and notched on opposite sides to admit the sample by capillary and allow air to escape out of the other side." Hodges '420 is applied in the identical manner.

2. Hodges '102 and Hodges '420

Hodges '102 and Hodges '420 (hereinafter, "Hodges") disclose an electrochemical cell comprising a polyester core (4) that defines an aperture (8). (Col. 4, lines 54-59) Adhered to one side of core (4) is a polyester sheet (1) having a sputter coating of palladium (2). The sheet (1) with palladium (2) covers aperture (8). A second polyester sheet (7) having a second sputter coating of palladium (6) is adhered to the other side of core (4). The second sheet (7) with the palladium (6) coating covers aperture (8). (FIGS. 9 and 10; Col. 4, line 59 - Col. 5, line 2)

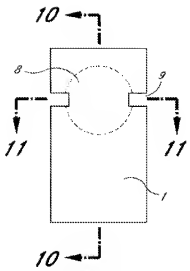


FIG. 9

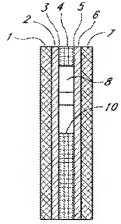


FIG. 10

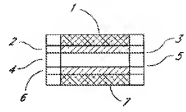


FIG. 11

The assembly is notched at (9) to provide for a solution to be admitted to the cell or to be drawn in by wicking or capillary action. (Col. 5, lines 3-5) As shown in FIGS. 10 and 11 and stated above, palladium layers (2 and 6) cover the aperture (8). In other words, Hodges shows a sandwich-type test strip in which the interior, circular chamber (8) is hidden by the outer palladium layers (2 and 6).

Therefore, Hodges neither teaches transparent or translucent viewing material nor does Hodges show a fill line that indicates sufficient filling of a test strip.

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hodges. Although claims 68 to 81 are individually patentable over Hodges, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Hodges does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Hodges '102 or Hodges '420

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Hodges fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Hodges shows a notch (9) that provides for a solution to be admitted to the electrochemical cell or to be drawn in by wicking or capillary action. (Col. 5, lines 3-5) As shown in FIGS. 10 and 11, palladium layers (2 and 6) cover the aperture (8). Hodges shows a sandwich-type test strip in which the interior, circular chamber (8) is hidden by the outer palladium layers (2 and 6).

Additionally, claims 68 to 81 are neither anticipated by Hodges nor rendered obvious by Hodges because Hodges teaches away from a visualization means associated with aperture (8) and the electrochemical cell. Instead, Hodges teaches the palladium (2 and 6) is applied as a sputter coating to give a *uniform coating thickness* on sheet (1) to cover the aperture (8). (Col. 4, lines 60-65, emphasis added) Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hodges. Although claims 82 to 95 are individually patentable over Hodges, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Hodges does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Hodges '102 or Hodges '420

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Hodges fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Instead, Hodges shows in FIGS. 10 and 11, palladium layers (2 and 6) cover the aperture (8). Hodges shows a sandwich-type test strip in which the interior, circular chamber (8) is hidden by the outer palladium layers (2 and 6).

Additionally, claims 82 to 95 are neither anticipated by Hodges nor rendered obvious by Hodges because Hodges teaches away from a solid, transparent, or translucent viewing material associated with aperture (8) and the electrochemical cell. Instead, Hodges teaches the palladium (2 and 6) is applied as a sputter coating to give a *uniform coating thickness* on sheet (1) to cover the aperture (8). (Col. 4, lines 60-65, emphasis added) Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hodges. Although claims 96 to 104 are individually patentable over Hodges, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104 and asserts that Hodges does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Hodges '102 or Hodges '420

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Hodges fail to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line

indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Hodges show palladium layers (2 and 6) cover the aperture (8). Hodges shows a sandwich-type test strip in which the interior, circular chamber (8) is hidden by the outer palladium layers (2 and 6).

Additionally, claims 96 to 104 are neither anticipated by Hodges nor rendered obvious by Hodges because Hodges teaches away from a solid, transparent, or translucent viewing material associated with aperture (8) and the electrochemical cell. Instead, Hodges teaches the palladium (2 and 6) is applied as a sputter coating to give a *uniform coating thickness* on sheet (1) to cover the aperture (8). (Col. 4, lines 60-65) Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

D. Rejection Under 35 U.S.C. §102(e) By U.S. Patent No. 5,798,031 (Charlton).

1. Office Action

The March 9, 2009, Office Action asserts that Charlton teaches an electrochemical glucose sensor in FIG. 1. March 9, 2009, Office Action, Page 4. The Office Action also asserts electrodes (38 and 39) have been read on the claimed "at least working and counter electrodes". The reagent layer (40) has been read on the claimed "test reagent". The claimed "capillary channel and a vent in fluid communication with the capillary channel…with a sample application port" has been read on the taught concave space (48) that admits the sample to a capillary action and vent (50).

2. Charlton Reference

Charlton shows a sensor (34) comprised of insulating base (36) upon which is printed in sequence (typically by screen printing techniques) an electrical conductor pattern (38), an electrode pattern (39 and 40), an insulating (dielectric) pattern (42), and finally a reagent layer (44). (Col. 2, lines 46-51) Lid (46) which provides a concave space (48) is punctured to provide air vent (50) and joined to base (36) in a sealing operation. (FIG. 1; Col. 3, lines 12-17)

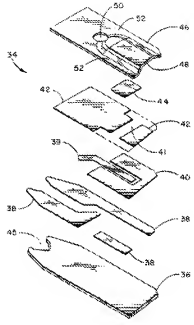


FIG. 1

"The lid is typically fabricated from a deformable polymeric sheet material such as polycarbonate or an embossable grade of polyethylene terephthalate, glycol modified polyethylene terephthalate or a metal foil composition such as an aluminum foil structure." (Col. 3, lines 55-60) Charlton does not disclose a line of demarcation or a fill line disposed on the lid and extending across the lid.

Charlton also teaches that the vertical and horizontal directions of the capillary space are critical for rapid movement of blood into the capillary space. There is no mention in Charlton of the longitudinal distance of the capillary space that a sufficient blood sample must travel as being critical.

> Col. 5, line 58 – Col. 6, line 5:
> In use, the sensor tip, containing the opening to the capillary space, is touched to a small drop of the fluid test sample which is typically blood produced by a finger prick. The blood is rapidly drawn up into the capillary space where the interaction with the enzyme is initiated and the instrument is signaled to initiate its timing sequence. It is essential that blood be drawn very rapidly into the capillary space, regardless of its spatial orientation in order that the timing sequence be initiated. The dimensions of the capillary space are typically on the order of 0.125 mm to 0.38 mm (0.005" to 0.015") in height and 2.5 mm to 3.75 mm (0.1" to 0.15") in width to facilitate the drawing of blood into the capillary space.

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Charlton. Although claims 68 to 81 are individually patentable over Charlton, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Charlton does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Charlton

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Charlton fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of

the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Charlton discloses a test strip having a base (36) and a lid (46), with the lid embossed to form a concave space (48) constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent and does not identify a fill line.

Additionally, claims 68 to 81 are neither anticipated by Charlton nor rendered obvious by Charlton because Charlton teaches away from a visualization means and a fill line associated with lid (46) of the electrochemical sensor. Instead, Charlton teaches "it is essential that blood be drawn very rapidly into the capillary space, regardless of its spatial orientation in order that the timing sequence be initiated." Charlton teaches using the electrochemical sensor in any *spatial orientation* therefore transparent or translucent material is not required for viewing a blood sample. Moreover, Charlton gives specific measurements for the vertical and horizontal dimensions of the capillary space to promote the rapid movement of the blood sample. However, Charlton is silent regarding the longitudinal dimension of the capillary space therefore Charlton does not disclose whether a sufficient sample size is less than the length of the capillary space. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Charlton. Although claims 82 to 95 are individually patentable over Charlton, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Charlton does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Charlton

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Charlton fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Charlton discloses a test strip having a base (36) and a lid (46), with the lid embossed to form a concave space (48) constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent and does not identify a fill line.

Additionally, claims 82 to 95 are neither anticipated by Charlton nor rendered obvious by Charlton because Charlton teaches away from a solid, transparent, or translucent viewing material and a fill line extending across a viewing area associated with lid (46) of the electrochemical sensor. Instead, Charlton teaches use of the electrochemical sensor in any *spatial orientation*. Moreover, Charlton gives specific measurements for the vertical and horizontal dimensions of the capillary space to promote the rapid movement of the blood sample, but Charlton is silent regarding the longitudinal dimension of the capillary space. In other words, Charlton teaches away from a user of the test strip visually identifying through a solid, transparent, or translucent viewing material and a fill line when a sufficient amount of blood sample has been collected because the test strip is to be used in any orientation and there are no longitudinal dimensions given to suggest a sufficient sample size collected in the capillary space is something less than the entire capillary space. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Charlton. Although claims 96 to 104 are individually patentable over Charlton, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104 and asserts that Charlton does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Charlton

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Charlton fails to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Charlton discloses a test strip having a base (36) and a lid (46), with the lid embossed to form a concave space (48) constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent and does not identify a fill line.

Additionally, claims 96 to 104 are neither anticipated by Charlton nor rendered obvious by Charlton because Charlton teaches away from a solid, transparent, or translucent viewing material and a fill line extending across the capillary channel associated with lid (46) of the electrochemical sensor. Charlton teaches away from a user of the test strip visually identifying through a solid, transparent, or translucent viewing material and a fill line when a sufficient amount of blood sample has been collected because the test strip is to be used in any orientation and there are no longitudinal dimensions given to suggest a sufficient sample size collected in

the capillary space. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

E. Rejection Under 35 U.S.C. §102(b) By U.S. Patent No. 5,575,895 (Ikeda) or U.S. Patent No. 5,264,103 (Yoshioka).

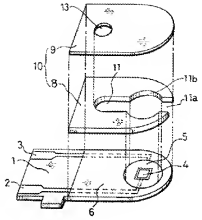
1. Office Action

The March 9, 2009, Office Action asserts that Ikeda teaches an electrochemical device for determination of glucose in a blood sample. March 9, 2009, Office Action, Page 5. The Office Action also asserts the insulating base plate (1) is provided with conductors (2, 3), working electrode (4), and counter electrode (5) that have been read on the claimed "at least working and counter electrodes". Reaction layer (7) in contact with the electrode system was read on the claimed "test reagent". Slotted spacer (8) provides a notch for sample acquisition and is in communication with channel (12) and vent (13) that has been read on the claimed "capillary channel and a vent in fluid communication with the capillary channel...with a sample application port". Yoshioka was applied in the identical manner.

2. Ikeda and Yoshioka References

Ikeda discloses a sandwich-type biosensor having a top base plate (1), a cover (9), and a slotted spacer (8). The slotted spacer (8) and cover (9) define a hollow space on the base plate (1) which constitutes a sample supplying channel (12). (Col. 4, lines 3-8) An entire reaction layer (7) is exposed to the hollow space (12), i.e., reaction layer (7) is placed in the arcuate part (11b) of the slot (11) including the sample supplying inlet (11a) of the sensor. (Col. 4, lines 18-25) The biosensor also includes an air vent (13) in cover (9) as illustrated in FIG. 2, reproduced below.

Fig. 2



There is no indication that any portion of base plate (1) or cover (9) is transparent or translucent, and there is no fill line in Ikeda.

In use, a sample enters the sample supplying inlet (11a) and travels along sample supplying channel (12) to the air vent (13) or the end of the channel (12), wherein the reaction layer (7) is dissolved in the sample liquid.

Yoshioka discloses a sandwich-type test strip with a base (2), spacer (3), and a cover (4) as illustrated in FIGS. 2 and 3. The base (2) comprises an electrical insulating substrate (1) made from polyethylene terephthalate, an electrode system formed on the substrate (1). (Col. 5, lines 3-8)

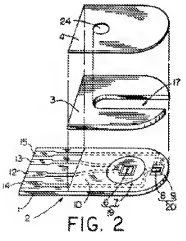


FIG. 2

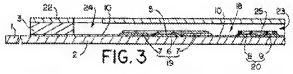


FIG. 3

There is no indication that any portion of base (2) or cover (4) is transparent or translucent, and there is no fill line in Yoshioka.

As shown in FIG. 2, the spacer (3) is formed in a U-shape and has a groove (17) that is open at one end thereof. When the spacer (3) and the cover (4) are laminated on the base (2), a passage (18) is formed. One end of the passage (18) is open to form a sample supply port (23) and the other end is also open to form an air port (24). (Col. 5, lines 30-38) In use, a sample enters the sample supply port (23) and travels along passage (18) to the air port (24) or the end of the passage (18), wherein the reaction layer (5) is dissolved in the sample liquid.

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ikeda or Yoshioka. Although claims 68 to 81 are individually patentable over Ikeda or Yoshioka, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Ikeda or Yoshioka do not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Ikeda or Yoshioka

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Ikeda and Yoshioka each fail to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such

that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Ikeda discloses a sandwich-type test strip with top and bottom layers (1 and 9) and an interior chamber (11, 11a, and 11b). Ikeda does not identify any solid portion(s) of top and bottom layers (1 and 9) as being transparent or translucent and does not identify a fill line.

Similarly, Yoshioka discloses a sandwich-type design with outer layers (2 and 4) and an interior chamber (18). Yoshioka does not identify any solid portion(s) of top and bottom layers (2 and 4) as being transparent or translucent and does not identify a fill line.

Additionally, claims 68 to 81 are neither anticipated by Ikeda (or Yoshioka) nor rendered obvious by Ikeda (or Yoshioka) because Ikeda (or Yoshioka) teaches away from a visualization means and a fill line associated with a cover layer of the electrochemical sensor. Ikeda and Yoshioka teach filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on the cover. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ikeda or Yoshioka. Although claims 82 to 95 are individually patentable over Ikeda or Yoshioka, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Ikeda or Yoshioka do not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Ikeda or Yoshioka

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Ikeda and Yoshioka each fail to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Ikeda discloses a sandwich-type test strip with top and bottom layers (1 and 9) and an interior chamber (11, 11a, and 11b). Ikeda does not identify any solid portion(s) of top and bottom layers (1 and 9) as being transparent or translucent and does not identify a fill line.

Similarly, Yoshioka discloses a sandwich-type design with outer layers (2 and 4) and an interior chamber (18). Yoshioka does not identify any solid portion(s) of top and bottom layers (2 and 4) as being transparent or translucent and does not identify a fill line.

Additionally, claims 82 to 95 are neither anticipated by Ikeda or Yoshioka nor rendered obvious by Ikeda or Yoshioka because Ikeda and Yoshioka teach away from a solid, transparent, or translucent viewing material and a fill line extending across a viewing area associated with a cover of the electrochemical sensor. Ikeda and Yoshioka teach filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on

the cover. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ikeda or Yoshioka. Although claims 96 to 104 are individually patentable over Ikeda or Yoshioka, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104 and asserts that Ikeda or Yoshioka does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Ikeda or Yoshioka

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Ikeda or Yoshioka each fail to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Ikeda discloses a sandwich-type test strip with top and bottom layers (1 and 9) and an interior chamber (11, 11a, and 11b). Ikeda does not identify any solid portion(s) of top and bottom layers (1 and 9) as being transparent or translucent and does not identify a fill line.

Similarly, Yoshioka discloses a sandwich-type design with outer layers (2 and 4) and an interior chamber (18). Yoshioka does not identify any solid portion(s) of top and bottom layers (2 and 4) as being transparent or translucent and does not identify a fill line.

Additionally, claims 96 to 104 are neither anticipated by Ikeda or Yoshioka nor rendered obvious by Ikeda (or Yoshioka) because Ikeda and Yoshioka teach away from a solid, transparent, or translucent viewing material and a fill line extending across a capillary channel of the electrochemical sensor. Ikeda and Yoshioka teach filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on the cover. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

F. Rejection Under 35 U.S.C. §102(e) By U.S. Patent No. 6,027,692 (Galen).

1. Office Action

The March 9, 2009, Office Action asserts that Galen teaches a test strip having a sample application port (20) along an edge having notch (19) that assures proper alignment in the detector. March 9, 2009, Office Action, Page 5. The Office Action also asserts the radiation blocking layers and contamination prevention layers have been read on the claimed "substantially opaque portion" and the "transparent window" respectively. (Col. 1, lines 30+)

2. Galen Reference

Galen discloses a glucose test device (15) that has a reagent pad (18) positioned by means of an adhesive (17) at one end of a plastic support member (16) having a notch (19) as shown in FIG. 3a, reproduced below. (Col. 42-47)

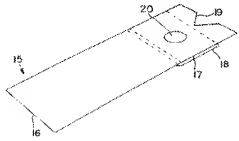


FIG. 3a

FIG. 2, reproduced below, also shows a test device with a support member (1) defining a sample aperture (6) and a support member (5) which has a detection aperture (11) and groove (12).

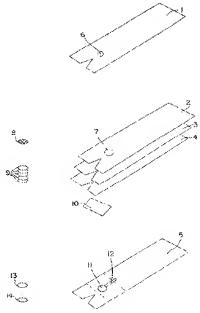


FIG 2

To use the glucose test device (19), a blood sample is applied to the hole (20 or 6) in the plastic support member (16 or 1). As the sample wets the membrane, the membrane reacts to generate color in proportion to the glucose in the blood sample. (Col. 16, lines 56-65)

Galen includes that if the support member is transparent, then there is no need for a detection aperture hence there would be no vent as required in claims 68-104. However, if the support member is non-transparent, then a detection hole is required to observe the color transition or fluorescence on the indicator layer.

> Col. 11, lines 53–63:
> The multi-layer device has at least one support member optionally having a detection aperture. As used herein the phrase "optionally having a detection aperture" means that where the one support member is transparent, there is no need for a detection aperture whereas with a non-transparent support member a detection aperture is needed and present. The detection aperture is a hole for observing the color transition or fluorescence on the indicator layer.

Galen teaches viewing the color transition on the indicator layer, not viewing an adequate sample size. Galen does not disclose a solid, transparent, or translucent viewing material to allow blood to be visualized as it fills a capillary channel and there is no fill line to indicate when sufficient filling has occurred.

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Galen. Although claims 68 to 81 are individually patentable over Galen, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Galen does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Galen

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Galen fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Galen discloses a top-dosing strip with an opening or hole (20, or 6) for receiving a blood sample. Galen does not identify any solid portion(s) of top and bottom layers (1 and 5 or 16) as being transparent or translucent along with a vent and does not identify a fill line. Instead, Galen discloses a hole that also allows a user to see a color change on the indicator layer.

Additionally, claims 68 to 81 are neither anticipated by Galen nor rendered obvious by Galen because Galen teaches away from a visualization means and a fill line associated with a cover layer of an electrochemical sensor. Galen teaches applying a sample to the opening or hole (20 or 6) in a top-dosing strip and observing the color change on the indicator layer through a detection aperture (11). There is no solid, transparent, or translucent viewing material over the detection aperture and fill line. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Galen. Although claims 82 to 95 are individually patentable over Galen, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Galen does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Galen

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Galen fails to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Galen discloses a top-dosing strip with an opening or hole (20, or 6) for receiving a blood sample. Galen does not identify any solid portion(s) of top and bottom layers (1 and 5 or 16) as being transparent or translucent along with a vent and does not identify a fill line. Instead, Galen discloses a detection aperture that allows a user to see a color change on the indicator layer.

Additionally, claims 82 to 95 are neither anticipated by Galen nor rendered obvious by Galen because Galen teaches away from a solid, transparent, or translucent viewing material and a fill line extending across a viewing area. Galen teaches applying a sample to the opening or hole (20 or 6) in a top-dosing strip and observing the color change on the indicator layer through a detection aperture (11). There is no covering over the hole (20 or 6) or detection aperture (11). Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Galen. Although claims 96 to 104 are individually patentable over Galen, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104 and asserts that Galen does not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Galen

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Galen fails to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length

of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Galen discloses a top-dosing strip with an opening or hole (20 or 6) for receiving a blood sample. Galen does not identify any solid portion(s) of top and bottom layers (1 and 5 or 16) as being transparent or translucent along with a vent and does not identify a fill line. Instead, Galen discloses a sample receiving opening or hole for application of the sample and visualization of a color change on the indicator layer through a detection aperture (11). The hole (20 or 6, 11) is simply not covered.

Additionally, claims 96 to 104 are neither anticipated by Galen nor rendered obvious by Galen because Galen teaches away from a solid, transparent, or translucent viewing material and a fill line extending across a capillary channel of the electrochemical sensor. Galen teaches applying a sample to a hole in a top-dosing strip and observing through a detection hole a color change on the indicator layer. There is no material over hole (20 or 6) as this would impede applying a sample to the strip. And Galen specifically teaches that a non-transparent layer must have a detection aperture while a transparent layer does not have a detection aperture. Without the detection aperture, there is no "vent" as required in the claims. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

G. Rejection Under 35 U.S.C. §102(b) By U.S. Patent No. 4,684,445 (Seshimoto), U.S. Patent No. 4,473,457 (Columbus), or U.S. Patent No. 5,798,031 (Ikeda).

1. Office Action

The March 9, 2009, Office Action asserts that Seshimoto, Columbus, or Ikeda teach an electrochemical test device with transparent and opaque portions, a conductive track, vents, and a sample application port. March 9, 2009, Office Action, Page 6.

Applicants believe there was a typographical error in the Office Action with respect to U.S. Patent No. 5,798,031 (Ikeda). Applicants believe U.S. Patent No. 5,798,031 issued to Charlton, not Ikeda, and the rejection by U.S. Patent No. 5,798,031 was addressed above.

2. Seshimoto and Columbus References

Seshimoto discloses a liquid guiding portion for guiding a reference liquid or a liquid sample to the surface of the ion-selective membrane (electrodes) having a pair of liquid receiving openings (12) defined in a top frame (18). The openings (12) are similar; therefore, for the sake of brevity only one opening (12) will be described. The opening (12) connects with a downward passage (13) for conveying the liquid downwardly to a lower level and a horizontal passage (14) for conveying the liquid in the horizontal direction just below the surface of ion-selective electrode sheets (11a, 11b, and 11c). The horizontal passage (14) connects with upward passages (15a, 15b, and 15c) for conveying the liquid upwardly to the ion-selective sheets. (FIGS. 1, 1A; Col. 4, line 65 - Col. 5, line 8)

FIG. 1

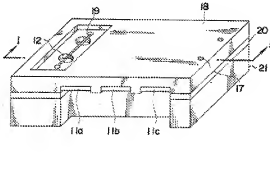
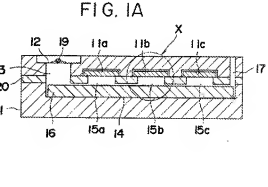


FIG. 1A



The two openings (12) (one opening for a reference liquid and the other opening for a liquid sample) are traversed by a bridge (19) to electrically connect both liquids of the reference liquid and the liquid sample to each other. (Col. 5, lines 25-33)

At the end of the horizontal passage (14) is an air vent (17). Assembled together are top frame (18), middle frame (20), and bottom frame (21), all made of plastic material. (Col. 5, lines 22-52) There is no indication that top frame (18), middle frame (20), or bottom frame (21) are transparent or translucent, and there is no fill line.

Columbus discloses a frame (12) formed by a pair of members (30) and (32) having opposing internal surfaces (34) and (36), respectively, forming transport surfaces for liquids via capillary movement. (Col. 3, lines 31-35) Access apertures (42) and (44) are formed in member (30) to admit the two liquids into zone (40). These apertures (42) and (44) have a shape that includes at least one corner to insure that a drop of liquid deposited at one of the apertures will enter the aperture and thus zone (40). (Col. 3, lines 55-60) Zone (40) transports the liquids towards each other in the portion (52). Arm portions (54) of zone (40) extend from bridge portion (52), thus giving zone (40) a horseshoe shape. (Col. 4, lines 11-15) A second zone of capillary transport is provided commencing with aperture (60). There is no indication that either top member (30) or bottom member (32) are transparent or translucent, and there is no fill line.

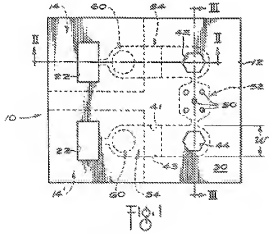


Fig. 1

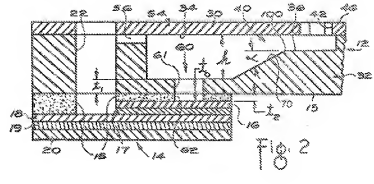


Fig. 2

3. Claims 68 to 81

Claims 68 to 81 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Seshimoto or Columbus. Although claims 68 to 81 are individually patentable over Seshimoto or Columbus, the novelty of independent claim 68 is sufficient to support the novelty of claims 69 to 81 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 68 to 81 and asserts that Seshimoto or Columbus do not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Seshimoto or Columbus

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Seshimoto or Columbus each fail to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode" and "said visualization means further includes ***a fill line*** extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 68. (emphasis added)

Seshimoto discloses a device having a bottom frame (21) and a top frame (18), with testing electrodes (11a-11c) received in an interior passage (14). A reference liquid sample is received at one opening (12) and a liquid sample is received in the other opening (12). Each sample is directed down through a corresponding passage (13) to one of the interiors (14). There is nothing in Seshimoto to suggest that any part of frame (21) or frame (18) is transparent or

translucent to allow viewing of either sample as it moves along interior passage (14). Seshimoto does not identify any solid portion(s) of top and bottom frames (21 and 18) as being transparent or translucent and does not identify a fill line.

Similarly, Columbus discloses a device in which a sample is received through apertures (42) and (44) and conveyed through a capillary channel defined by surfaces (34) and (36) (Col. 3, lines 31-65). There is no indication that the top (30) (including surface 34) or the bottom (32) (including surface 36) is transparent or translucent. Columbus does not identify any solid portion(s) of top and bottom layers (30 and 32) as being transparent or translucent and does not identify a fill line.

Additionally, claims 68 to 81 are neither anticipated by Seshimoto (or Columbus) nor rendered obvious by Seshimoto (or Columbus) because Seshimoto (or Columbus) teaches away from a visualization means and a fill line associated with a cover layer of the electrochemical sensor. Seshimoto teaches an adequate sample size is obtained by filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on the cover. Columbus teaches two-way filling of an interior chamber with a sample by appropriately choosing dimensions of apertures and internal chambers thereby obviating the need for any visual indicators on the top. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

4. Claims 82 to 95

Claims 82 to 95 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Seshimoto or Columbus. Although claims 82 to 95 are individually patentable over Seshimoto or Columbus, the novelty of independent claim 82 is sufficient to support the novelty of claims 83 to 95 without the need to individually argue each claim, and these claims are therefore

grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 82 to 95 and asserts that Seshimoto or Columbus do not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Seshimoto or Columbus

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Seshimoto or Columbus each fail to disclose "***a solid, transparent, or translucent viewing material*** extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode" and "said strip body further including ***a fill line extending across the viewing area*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 82. (emphasis added)

Seshimoto discloses a device having a bottom frame (21) and a top frame (18), with testing electrodes (11a-11c) received in an interior passage (14). A reference liquid sample is received at one opening (12) and a liquid sample is received in the other opening (12). Each sample is directed down through a corresponding passage (13) to one of the interiors (14). There is nothing in Seshimoto to suggest that any part of frame (21) or frame (18) is transparent or translucent to allow viewing of either sample as it moves along interior passage (14). Further, Seshimoto does not identify a fill line.

Columbus discloses a device in which a sample is received through apertures (42) and (44) and conveyed through a capillary channel defined by surfaces (34) and (36) (Col. 3, lines 31-65). There is no indication that the top (30) (including surface 34) or the bottom (32) (including surface 36) is transparent or translucent. Further, Columbus does not identify a fill line.

Additionally, claims 82 to 95 are neither anticipated by Seshimoto (or Columbus) nor rendered obvious by Seshimoto (or Columbus) because Seshimoto (or Columbus) teaches away from a solid, transparent, or translucent viewing material and a fill line extending across a viewing area. Seshimoto teaches an adequate sample size is obtained by filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on the cover. Columbus teaches two-way filling of an interior chamber with a sample by appropriately choosing dimensions of apertures and internal chambers thereby obviating the need for any visual indicators on the top. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

5. Claims 96 to 104

Claims 96 to 104 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Seshimoto or Columbus. Although claims 96 to 104 are individually patentable over Seshimoto or Columbus, the novelty of independent claim 96 is sufficient to support the novelty of claims 97 to 104 without the need to individually argue each claim, and these claims are therefore grouped together for the purpose of a concise appeal. Applicant respectfully traverses the rejection of claims 96 to 104 and asserts that Seshimoto or Columbus do not teach or suggest all the claim limitations.

a. "Solid, transparent, or translucent viewing material" and "fill line" are not disclosed in Seshimoto or Columbus

Applicant submits that the Office has failed to present a *prima facie* case of anticipation. Accordingly, Applicant respectfully traverses the anticipation rejection.

Seshimoto or Columbus each fail to disclose "***said strip body including a solid, transparent, or translucent viewing material*** overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area" and "***a fill line extending across the capillary channel*** at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test" as recited in independent claim 96. (emphasis added)

Seshimoto discloses a device having a bottom frame (21) and a top frame (18), with testing electrodes (11a-11c) received in an interior passage (14). A reference liquid sample is received at one opening (12) and a liquid sample is received in the other opening (12). Each sample is directed down through a corresponding passage (13) to one of the interiors (14). There is nothing in Seshimoto to suggest that any part of frame (21) or frame (18) is transparent or translucent to allow viewing of either sample as it moves along interior passage (14). Further, Seshimoto does not identify a fill line.

Columbus discloses a device in which a sample is received through apertures (42) and (44) and conveyed through a capillary channel defined by surfaces (34) and (36) (Col. 3, lines 31-65). There is no indication that the top (30) (including surface 34) or the bottom (32)

(including surface 36) is transparent or translucent. Further, Columbus does not identify a fill line.

Additionally, claims 96 to 104 are neither anticipated by Seshimoto (or Columbus) nor rendered obvious by Seshimoto (or Columbus) because Seshimoto (or Columbus) teaches away from a solid, transparent, or translucent viewing material and a fill line extending across a viewing area. Seshimoto teaches an adequate sample size is obtained by filling the interior chamber with a sample until the sample reaches a vent thereby obviating the need for any visual indicators on the cover. Columbus teaches two-way filling of an interior chamber with a sample by appropriately choosing dimensions of apertures and internal chambers thereby obviating the need for any visual indicators on the top. Therefore, a proper case of anticipation and/or obviousness has not been established. Withdrawal of this rejection is thus solicited.

VIII. APPENDIX OF CLAIMS

(37 CFR § 41.37(c)(1)(viii))

The text of the claims involved in the appeal are:

1-67. (Cancelled)

68. (Previously submitted) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port to at least the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface;

a test reagent adjacent at least the working electrode; and

visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent, or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,

said visualization means further includes a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

69. (Previously submitted) The test strip of claim 68 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

70. (Previously submitted) The test strip of claim 69 in which the fill line extends at a location between the working electrode and the vent.

71. (Previously submitted) The test strip of claim 70 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

72. (Previously submitted) The test strip of claim 68 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

73. (Previously submitted) The test strip of claim 72 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

74. (Previously submitted) The test strip of claim 73 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

75. (Previously submitted) The test strip of claim 68 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

76. (Previously submitted) The test strip of claim 75 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge surface of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent, or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

77. (Previously submitted) The test strip of claim 75 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.

78. (Previously submitted) The test strip of claim 77 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

79. (Previously submitted) The test strip of claim 78 in which the opaque portions are defined by the roof.

80. (Previously submitted) The test strip of claim 75 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material.

whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.

81. (Previously submitted) The test strip of claim 80 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

82. (Previously submitted) An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising:

a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port at least to the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface; and

a test reagent adjacent at least the working electrode;

a solid, transparent, or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample

application port, up to and including said working electrode and at least a portion of said counter electrode,

the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test,

said strip body further including a fill line extending across the viewing area at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

83. (Previously submitted) The test strip of claim 82 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

84. (Previously submitted) The test strip of claim 83 in which the fill line extends at a location between the working electrode and the vent.

85. (Previously submitted) The test strip of claim 84 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

86. (Previously submitted) The test strip of claim 82 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

87. (Previously submitted) The test strip of claim 86 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

88. (Previously submitted) The test strip of claim 87 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

89. (Previously submitted) The test strip of claim 82 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

90. (Previously submitted) The test strip of claim 89 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the

second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge surface of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent, or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

91. (Previously submitted) The test strip of claim 89 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.

92. (Previously submitted) The test strip of claim 91 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

93. (Previously submitted) The test strip of claim 92 in which the opaque portions are defined by the roof.

94. (Previously submitted) The test strip of claim 89 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,

whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.

95. (Previously submitted) The test strip of claim 94 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.

96. (Previously submitted) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge surface, the capillary channel extending from the sample application port to at

least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;

at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge surface;

a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;

said strip body including a solid, transparent, or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;

said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; and

a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.

wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

97. (Previously submitted) The test strip of claim 96 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

98. (Previously submitted) The test strip of claim 96 in which the fill line extends at a location between the working electrode and the vent.

99. (Previously submitted) The test strip of claim 98 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

100. (Previously submitted) The test strip of claim 96 in which the fill line extends at a location between the test area and the vent.

101. (Previously submitted) The test strip of claim 100 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.

102. (Previously submitted) The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

103. (Previously submitted) The test strip of claim 96 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge surface to the electrodes.

104. (Previously submitted) The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

IX. APPENDIX OF EVIDENCE

(37 CFR § 41.37(c)(1)(ix))

None.

X. APPENDIX OF RELATED DECISIONS

(37 CFR § 41.37(c)(1)(x))

None.

Respectfully submitted,

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